BSD-2000/3D/MR Deep Regional Hyperthermia System

MRI - 60cm bore 1.5 Tesla

FEATURES

Annular Phased Array
RF Power Delivery System
Treatment Planning & Control Software
Applicator Subsystem
12 Channel Configuration
8-port Temperature Monitoring
Water Circulation System

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What is Image Guided Hyperthermia?

The BSD-2000/3D/MR provides deep regional therapeutic hyperthermia to solid tumors by applying radio-frequency (RF) energy at a frequency 100 MHz. The system delivers energy to a patient using a power source and an array of multiple antennae that surround the patient's body.

The addition of MRI (Magnetic Resonance Imaging) provides visualization allowing for accurate placement of the heat zone and assurance of target temperature optimization. Heating and imaging can be done simultaneously for live temperature management.

The operator can steer the heat zone in the X, Y an Z axis by utilizing the adjustment of frequency, phase and amplitude from multiple power sources. Energy can be focused electronically to the tumor region, thus providing dynamic control of the heating by the operator without repositioning the patient.

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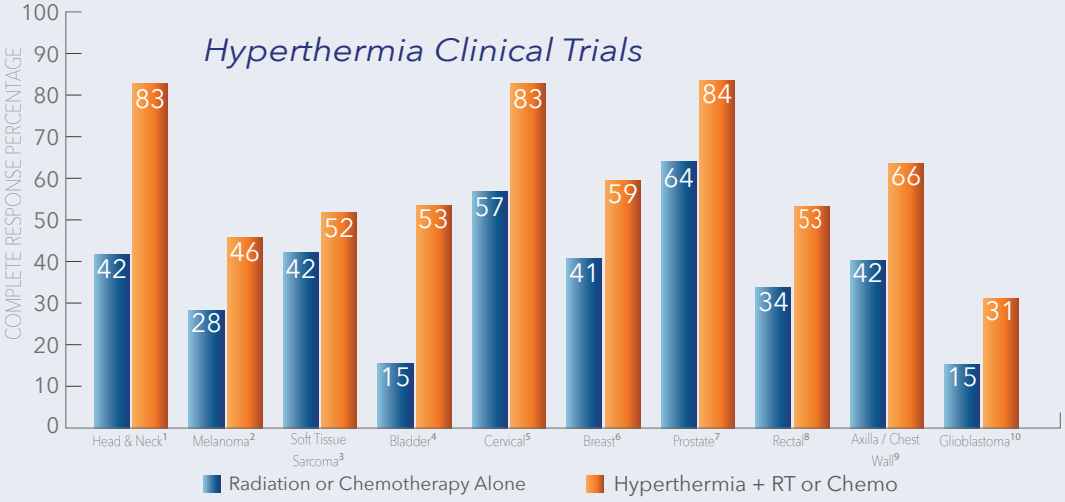
The Hyperthermic Effect

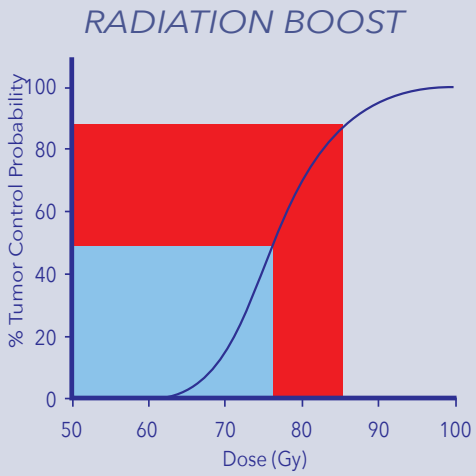
Hyperthermia and Radiotherapy

Hyperthermia increases the effectiveness of radiation therapy due to the independent cytotoxic effects of hyperthermia combined with its radio-sensitizing effects. Hyperthermia increases blood flow, resulting in improved tissue oxygenation and thus increased radio-sensitivity. Hyperthermia also interferes with cellular repair of the DNA damage caused by radiation. Hyperthermia damages cells that are hypoxic, have a low pH, and are in the S-phase of division, which are all conditions that make cells resistant to radiation therapy. The addition of hyperthermia does not usually increase the toxicity of radiation therapy..

Hyperthermia and Chemotherapy

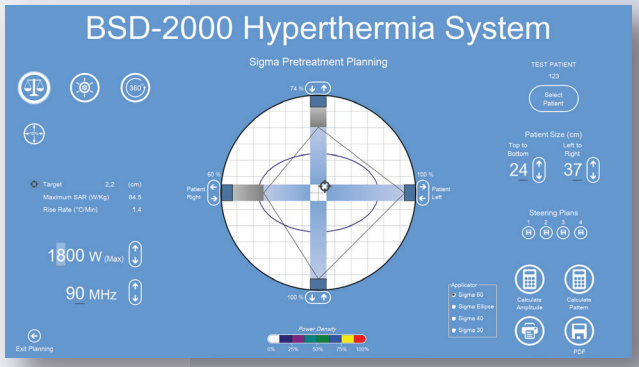
Hyperthermia increases the effectiveness of chemotherapy by increasing blood flow and perfusion to the tumor site. Increased blood flow also means higher concentration of the target drug to the tumor. A recently reviewed dual arm phase III study of 341 soft tissue sarcoma patients showed significant benefits of adding hyperthermia to the treatment protocol. Those patients receiving hyperthermia along with chemotherapy experience a higher rate of complete tumor response and a significant increase in the long-term survival rate.



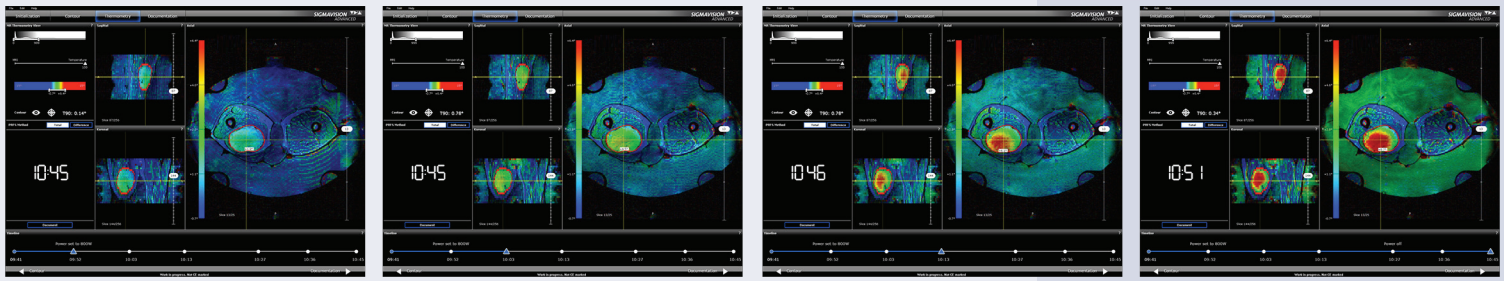


Treatment Planning and Simulation

Treatment planning and simulation software is provided with the entire line of Pyrexar hyperthermia treatment systems. The easy access, touch screen enabled, application puts energy distribution and control at your finger tips. Once patient prescribed dosage is entered, set-up, recall and real-time temperature management are available.



BSD-2000 Screen Capture



MRI images demonstrate the heating effectiveness of the BSD-2000/3D/MR Deep Regional Hyperthermia System. Necrotic tumor tissue naturally absorbs heat, while healthy tissue channel heat away from the target area with the help of the bodies circulatory system, keeping healthy organs safe. (Soft Tissue Sarcoma of the leg)

Clinical Trial Results show in chart above represent all hyperthermia devices

[1]Huilgol et al.,2010 | [2]Overgaard et al.,1995 | [3]Issels, et al.,2018 | [4]Colombo et al.,2011 | [5]Van der Zee et al.,2000
[6]Vernon et al.,1996 | [7]Hurwitz et al.,2011 | [8]Berdov et al.,1990 | [9]Jones et al.,2005 | [10]Sneed et al.,1996

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Indication for Use

The BSD-2000 Hyperthermia System is intended for use in conjunction with standard radiotherapy for the treatment of cervical carcinoma patients who would normally be treated with combined chemotherapy and radiation but are ineligible for chemotherapy due to patient related factors.

Procedure for Administration of Hyperthermia in Conjunction with Ionizing Radiation Therapy

Hyperthermia is administered during the delivery of standard radiotherapy, typically once per week, to a total of 5 treatments. The patients can be given Xanax 30 minutes prior to the treatment. The treatment objective is to deliver hyperthermia for 60 minutes after interstitially measured tumor temperature have reached a minimum of 42°C, or for a maximum total duration of 90 minutes. When temperatures of 42°C are reached in one or more locations inside the tumor, or after 30 minutes, the 60 minute hyperthermia treatment time period begins. The temperature elevation for normal tissues should be limited to 43°C, with the exception of subcutaneous fat tissue situated >1 cm from the skin, where 44°C is acceptable.

Contraindications

Patients who have implanted, worn or carried medical devices, including cardiac pacemakers, implanted defibrillators, infusion pumps, insulin pumps, cardiac monitoring electrodes and devices, deep brain stimulators, cochlear implants, radio-frequency identification devices attached to devices, or any other implanted active electronic device or monitoring system

- A body diameter >49 cm from left to right
- Severe dysfunction of the heart or lungs
- Severe pulmonary disease with a forced expiratory volume (FEV) <50%
- Patients who cannot adequately respond to pain (those with significant neuropathies)
- Patients who have had prior irradiation to the treatment site
- Patients who are less than 21 years of age
- Known decrease in circulation in the heated area produced by any means (i.e., vasoconstrictive drugs, DIC, ischemia or other cause)
- Patients who have electrically conductive, metal, or foreign objects in or on or attached to their body
- Unstable angina pectoris (under medication) with imminent threat of an infarction
- Myocardial infarction <6 months ago
- Cardiac decompensation necessitating medication
- Arrhythmia necessitating medication
- Heart rate >90bpm
- Hypertension: diastolic >100 mmHg and/or systolic >180 mmHg, while using medication
- Hypotension: diastolic <50 mmHg and / or systolic <90 mmHg
- Severe cerebrovascular disease: multiple cerebrovascular accidents (CVA) or a CVA <6 months before treatment
- Inability to place either an intratumoral or an intraluminal temperature sensor for monitoring of tumor indicative temperatures

Clinical Warnings

Hyperthermia treatment with the BSD-2000 can significantly increase the whole body temperature of the patient. A Vital Signs Monitor (VSM), not supplied by BSD, must always be used during treatments with the BSD-2000 System to monitor the patient's vital signs. Emergency cardiopulmonary resuscitation and hypothermia inducing supplies should be readily available during treatments.
Systemic heating over 40°C may induce a general thermo-regulatory response exceeding the patient's compensatory capabilities and may cause injury to sensitive organs such as liver or brain.
Hyperthermia treatment should not be delivered if the patient's heart rate prior to start of treatment is >90 bpm or if patient's Systolic Blood Pressure (BP) is: >140 mmHg or <100 mmHg or diastolic BP is: >90 mmHg or <60 mmHg.

The following vital signs dictate reduction of applied power and/or cessation of treatment:

- Pulse >160
- Blood Pressure:
- Systolic > 180 mmHg – diastolic > 100 mmHg
- Systolic < 90 mHg – diastolic < 50 mmHg

If adequate blood flow is not present within the normal tissue located near the tumor area, excessive heating of the normal tissue may occur. Hyperthermia should not be used on patients with decreased circulation, which may be caused by vasoconstrictive drugs, disseminated intravascular coagulation (a blood clotting disorder), ischemia or other medical condition. Reduced blood flow can occur in areas that have scar tissue from surgery or in organs that contain stagnant fluid, such as the urinary bladder. If these types of tissues are located near the tumor area, an invasive temperature sensor can be placed to monitor heating in the normal tissue areas located near the targeted treatment area. Large thermal doses (a continued elevation of moderately high temperature or a short extreme elevation of temperature) in normal tissue situated in the vicinity of the treated tumor or between the tumor and the body surface may result in regions of thermal aseptic necrosis that require medical intervention and that may not be apparent on inspection of the skin.

The BSD-2000 System temperature sensors and the invasive E-Field sensor are not sterile and must be inserted into tissue using a closed-end catheter to prevent infection. Temperature sensors must never be inserted directly into the tissue.
The depths at which temperature sensors must be placed for hyperthermia frequently require that monitoring sites be locally anesthetized prior to treatment for catheter insertion. However, when administering hyperthermia treatments, the use of analgesics and tranquilizers is appropriate when needed, but under no circumstance is a general anesthesia or regional block to be used. Most agents used for anesthesia are derivatives of the 'caine' group of drugs, and caine derivatives are heat sensitizers and should be avoided during hyperthermia treatment.

Caution should be taken when working around the head and neck area of the patient to avoid exposing the eyes to stray EM energy.
The energy from the BSD-2000 System and applicators used with the system can present a risk to patients and to operators. Individuals who have a pacemaker or other active device implants or a metallic implant should not be inside the shielded treatment chamber during RF power output at any level. To prevent RF power output interference with active device implants, always leave the interlock door open when any individual who has an active device that is implanted, worn or carried is inside the shield room.

Metallic implants that are located in or on or attached to the patient's body may be excessively (and preferentially) heated or may contribute to excessive heating of the tissues contacting the metal implant or the electrical conductors and this may cause severe burns and patient injury.

A filled bolus contains a large volume of water that could cause the silicone bolus membrane to quickly tear if punctured. The water would then be released onto the patient. Because of this possibility, all punctures to the bolus membrane must be repaired immediately.
The bolus membrane can rupture while in use. The physician should ensure the sterility of the treatment surface if, in their medical judgment, it is necessary. It is BSD Medical's recommendation that any body hair that may press into the bolus membrane be removed prior to treatment.

Equipment/Electrical Warnings

Vital signs monitoring during hyperthermia treatment is restricted to heart rate, blood pressure, pulse, and core temperature using pneumatic measurement techniques. Cardiac monitoring devices, pulse oximeters, or other devices that utilize electrodes or wires should not be used during hyperthermia treatment as the energy from the BSD-2000 can interfere with the results and preferentially heat the electrodes and tissues in contact with the electrically conductive materials.
The energy from the BSD-2000 System and applicators used with the

system can interfere with vital signs monitoring (VSM). The power output should be discontinued during monitoring of vital signs or the VSM electronics should be located outside of the shielded room.
Circuits in the BSD-2000 System are capable of electrical ignition of flammable liquids, anesthetics, gases, and vapors. The ignition of these materials can result in fires and/or explosions causing serious injury or death and/or property damage. Never operate the BSD-2000 System in the presence of flammable anesthetics or liquids and explosive gases or vapors. The possibility of relay contact arcing exists during operation that may ignite any flammable liquids, explosive gases, or vapors.

Burns can result from accidental contact with coaxial cables and connectors. Operators must not make adjustments to the cabling or connectors when EM energy is applied.

EM fields can cause heating of the body inside the shielded treatment room.

The E-fields should be measured to determine the potential exposure hazard. Levels over 1 mW/cm2 should be avoided for periods of exposure over six minutes per hour for everyone except the patient. A hazard meter should be used to detect and monitor stray field levels.
To avoid possible electric shock while cleaning the BSD-2000 System, disconnect the system from the power source before cleaning its surfaces. Do not allow moisture to enter the electrical assemblies
The BSD-2000 System OFF control circuit can fail. If any light, monitor, or other visual indicator stays on after turning the system off, it is possible for any of the power-on hazards (electrical shock, electrical ignition, etc.) to exist. To prevent possible serious injury or death from any potential hazard, operator or service personnel must unplug the main power cable to the control console, amplifier, and other equipment.

Precautions

Adhere to the recommended procedures for temperature sensor placement and selection of control sensor. This will minimize the probability of excessive temperature in normal tissue or of inadequate treatment temperature in the tumor.
Cervical cancer treatments utilize temperature sensor(s) placed in catheters that have been inserted into natural orifices (intraluminal); i.e., rectum, urethra (bladder), and vagina, to estimate the regional temperature distribution. Published studies have demonstrated that the temperatures measured within a natural orifice that is adjacent to a tumor are representative of the temperatures obtained in the tumor.
For cervical patients, vaginal temperatures are cervical tumor indicative; rectal and bladder temperatures are normal tissue indicative.
Interstitial or intratumoral thermometry may increase the risk of discomfort, pain, bleeding, severe infection, and tumor seeding. The procedure may also decrease patient tolerance and thus the ability to deliver the prescribed number of hyperthermia treatments. Thus, the ability to directly place temperature sensors in tumor and normal tissues may be limited.
Observe strict adherence to aseptic techniques during the invasive placement of temperature sensor insertion catheters. This will help to avoid infections. Instruct all patients in the daily care of indwelling catheters and sensor sites to prevent sepsis.

Verify calibration of temperature sensors daily, or as used, to ensure accurate temperature monitoring during treatments.

Adhere to recommended applicator placement and bolusing practices to reduce the likelihood of surface burns and blistering from the subsequent delivery of therapeutic heat.

Monitor closely physiological indicators of excessive heat delivery.

Cautions

Temperature sensors and the invasive E-Field sensor are not sterile and must be inserted into tissue using a closed-end catheter to prevent infection. Temperature sensors must never be inserted directly into the tissue.

Fluid spills on the equipment can cause severe equipment damage and/or serious injury or death due to electrical shock. Never place fluids on the BSD-2000 console. Use good judgment in protecting the equipment from fluids when treating a patient.
Damage to the bolus membrane will result if silicone grease lubricants are placed on the bolus membrane surface. Avoid staining the bolus membrane with iodines and Betadine.

Use caution when working with the bolus to prevent damaging the bolus membrane by impacts, puncturing, or localized stress.
The use of accessories, applicators, and cables other than those included with the BSD-2000, with the exception of applicators and cables sold by BSD Medical as replacement parts for internal components, may result in increased emissions or decreased immunity of the BSD-2000 System.

The BSD-2000 System should not be used adjacent to or stacked with other equipment. If the BSD-2000 is used with or stacked with other equipment, the BSD-2000, as well as the other equipment, should be tested to verify normal operation in the configuration in which it will be used.

If unauthorized maintenance of the BSD-2000 System should be performed, it is possible that there will be a significant change in the heating characteristics of the system and burns could result.
Operators must not remove the covers of the BSD-2000 System or attempt to perform any maintenance other than the periodic maintenance outlined in the Maintenance Section of the Operator Manual.
Do not use the equipment in an explosive atmosphere.

Essential Prescribing Information and Abbreviated Instructions for Use

The BSD-2000 System uses voltages that are potentially lethal. Use extreme caution when performing maintenance of the BSD-2000 System.

Do not operate an electronic device or equipment emitting electromagnetic energy in proximity to the BSD-2000 System during a hyperthermia procedure, as the electronic equipment may interfere with the operation of the BSD-2000 System.

For pre-sterilized closed-tip insertion catheters, do not use if the integrity of the catheter package has been broken. For insertion catheters supplied without pre sterilization, follow the manufacturer's sterilization recommendations. BSD does not supply insertion catheters.

The operator should NOT restore the system files or the registry information unless they are sure this data should be overwritten. Once restored, the old data is lost.

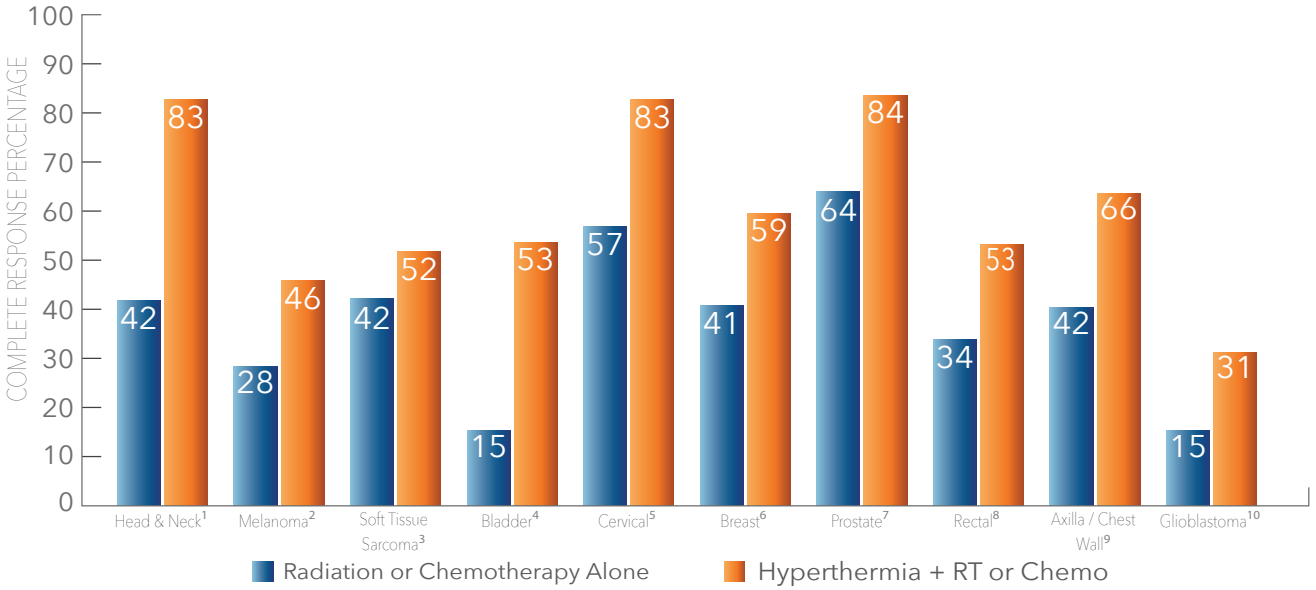
When handling the temperature sensors, the operator SHOULD NOT ·
Touch the connector white plastic surface with your fingers
· Spill liquids at or near the connector sites
· Pull or stretch the temperature sensors
· Sharply bend or kink the temperature sensors
· Force a temperature sensor into a catheter

When handling the temperature sensors, the operator SHOULD: ·
Properly align the sensor connector without applying force
· Handle temperature probes with care
· Store temperature sensors in a safe place when not in use
· Place the protective cap over the sensor connector when it is not connected to the temperature interface box

EM fields can cause heating of the body inside the shielded treatment room. The E-fields should be measured to determine the potential exposure hazard. Levels over 1mW/cm2 should be avoided for periods of exposure over six minutes per hour for everyone except the patient.
A hazard meter should be used to detect and monitor stray field levels.
Remove large metal objects from the treatment room to prevent resonance excitation of these objects.

Keep all cables straight and free from entanglement and avoid use of rubber coated cables.

Hyperthermia Clinical Trials Citations



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